

DC-STEP | Discontinuation/Closeout Form

ID Number: _____

This form is to be completed for any subject who withdraws from any study component (intervention and/or telephone interviews), is terminated from study activities, or completes study activities as per protocol. Approval must be obtained from your Task Manager.

1. Indicate study: 1 ☐ **NRT Study** 2 ☐ **ETS Study**
2. Date of termination: |__|__| - |__|__| - 2 0|__|__|
3. Date of last contact with this participant: |__|__| - |__|__| - 2 0|__|__|
4. Nature of last contact with this participant:
1 ☐ Intervention Session (clinic or phone) 2 ☐ CNMC Telephone Interview 3 ☐ Home Visit (ETS only)
4 ☐ Retention Activities (Locator Information Update/Tracking Efforts)
5 ☐ Other (SPECIFY) _____

5. Reason(s) for discontinuation/closeout (MARK ALL THAT APPLY)

ETS or NRT

- 1 ☐ Subject claimed to be non-cigarette smoker/non-ETS exposed
- 2 ☐ Subject not Black, African American or Hispanic
- 3 ☐ Subject found to be under 18 years of age at recruitment
- 4 ☐ Subject does not live in DC metro area
- 5 ☐ Subject found to be suicidal/psychotic
- 6 ☐ Subject incarcerated
- 7 ☐ Subject (mother) deceased
- 8 ☐ Subject lost to follow up
- 9 ☐ Subject unavailable for study activities (moved out of the area, transferred to another clinic)
- 10 ☐ Subject delivered before required baseline activities completed
- 14 ☐ Subject requested withdrawal from study activities
- 15 ☐ Completed as per protocol

NRT Only

- 17 ☐ Subject enrolled at >24 weeks gestation

ETS Only

- 19 ☐ Subject enrolled at >35 weeks gestation
- 20 ☐ Infant deceased, including stillbirth, miscarriage, abortion
- 21 ☐ Mother hospitalized > 7 days following delivery
- 22 ☐ Infant in NICU (or NICU step-down clinic) for > 12 hours
- 23 ☐ Infant born less than 34 weeks of age
- 24 ☐ Infant birth weight less than 1800 grams
- 25 ☐ Mother lost custody of child
- 26 ☐ Withdrawal from addictive substances requiring methadone treatment or hospitalization, mother in substance abuse or other treatment facility
- 27 ☐ Mother/child living in group home, shelter, homeless or other transitional housing

28 ☐ **Other Reason** → 28a. SPECIFY _____

6. Please provide details to further explain the reason for this termination/withdrawal/closeout:

7. Was reason for this termination/withdrawal/closeout an adverse event? 1 ☐ Yes 2 ☐ No

7a. If adverse event, record adverse event code here: _____

Requested by:

Name of Requestor

Signature of Requestor

Date Signed |__|__| - |__|__| - 2 0 |__|__|

Approved by:

Name of Task Manager

Signature of Task Manager

Date Signed |__|__| - |__|__| - 2 0 |__|__|